

# PSJ3

## Exhibit 296

**To:** Shamblen, Randy[Randy.Shamblen@pharma.com]; Kupper, Robert[Robert.Kupper@pharma.com]; Loewenstein, Robert[Robert.Loewenstein@pharma.com]; Brown, Charles[Charles.Brown@pharma.com]; Nadeau, Albert[Albert.Nadeau@pharma.com]  
**Cc:** Mancinelli, Vincent[Vincent.Mancinelli@pharma.com]; Fogel, David[David.Fogel@pharma.com]; DiNicola, Walter[Walter.Dinicola@pharma.com]; Brinton, Alan[Alan.Brinton@pharma.com]; Doyle, James[James.Doyle@pharma.com]; Julian, Melissa[Melissa.Julian@pharma.com]  
**From:** Crowley, Jack  
**Sent:** Thur 7/21/2011 11:49:35 AM  
**Subject:** Quota issues - Registration Fee Increase by DEA  
[2011-16847.pdf](#)  
[Letter to DEA 062911.pdf](#)  
[email to ASAC Yrizarry.docx](#)  
[NJPIG updated Letter to DEA 072011.pdf](#)

Dear All:

I will send several emails on this topic. A near term solution may be difficult without pulling out all the stops.

First of all, we are attempting to reason with DEA through the New Jersey Pharmaceutical Industry Group on the quota issue. In actuality, we are simply trying to get a group of companies on the record as asking DEA to address this critical issue - so that this can be used as ammunition in the future.

We are working with the DEA Newark Office to advocate on behalf of industry, although we have encountered some delaying tactics.

Individual companies are ready to barrage Joe Rannazzisi very soon. I'm not sure he has an appreciation of just how jittery industry is.

Additionally, we should use the opportunity to comment on the proposed increase in registration fees to voice industry's concerns.

The proposal was published in the Federal Register on July 6<sup>th</sup>. (39318 Federal Register / Vol. 76, No. 129 / Wednesday, July 6, 2011 / Proposed Rules)

DEA is proposing to increase our registration fees by 33%. Comments must be received within 60 days of this Notice of Proposed Rule Making.

My thought is that it's an opportunity to remind DEA that our fees should guarantee good customer service in the processing of quota requests. That's a basic function - most important to Industry - that has been allowed to deteriorate to a critical point.

Those who choose to comment would not be complaining about the increase - but would be insisting that the quota unit be beefed up in terms of competent headcount as part of the increase.

DEA needs to deal with the reality of the challenges facing the quota unit - in addition to beefing up all of its Tactical Diversion Squads nationally, which is their main focus.

It's a chance to remind them that their core mission includes customer service to the industry in terms of quota processing.

Industry has experienced extended response times to requests for quota increases submitted to DEA's UN Reporting and Quota Section/ODQ. Prior to changes in the quota review process, DEA has striven to achieve an average 30 business day cycle time; however in 2011 this has increased to 45 business days or 50% more time as a result of the additional departmental reviews outside ODQ. As a consequence, quota requests now may take as long as 9 weeks or more (13-15 weeks is getting close to the new norm).

There is a major staffing issue with that unit.

We have been advised that the additional time is due to a new interpretation that the current regulations do not support the review/sign off process to be solely within the authority of ODQ and therefore additional time is necessary to allow for departmental reviews outside the ODQ group to include (but not limited to): Registration, Suspicious Order Monitoring and potentially other DEA staff to address special issues, as well as final review by the Office of Chief Counsel.

As you can appreciate, any delay is a potential hindrance to industry to provide for an uninterrupted supply of medication to healthcare providers.

Best regards,

Jack

Jack Crowley  
Executive Director  
CSA Compliance  
Purdue Pharma L.P.  
One Stamford Forum  
Stamford, CT 06901-3431  
(203) 588-8613 (Stamford, CT)  
(252) 265-1964 (Wilson, NC)  
(203) 273-2656 (cell)  
[jack.crowley@pharma.com](mailto:jack.crowley@pharma.com)